GOVERNMENT OF INDIA
CHEMICALS AND FERTILIZERS
LOK SABHA

UNSTARRED QUESTION NO:3361
ANSWERED ON:06.09.2007
IMPORTED FORMULATIONS
Hasan Chaudhary Munawwar

Will the Minister of CHEMICALS AND FERTILIZERS be pleased to state:

(a) Whether NPPA had been following the dual policy of MAPE of 35%&50% increase of finished imported formulations;

(b) if so, whether DCGI had granted a certificate to Novartis and on the basis of this non-availability certificate, NPPA had allowed 50% MAPE;

(c) if so the details thereof alongwith the names of the formulations;

(d) whether NPPA had later withdrawn the 50% MAPE on the Novartis imported formulations; and

(e) if so, the details and the steps taken by the Government to ask the companies to pay the over charged amount in respect of this formulation

Answer

MINISTER OF STATE IN THE MINISTRY OF CHEMICALS AND FERTILIZERS AND MINISTER OF STATE IN THE MINISTRY OF PARLIAMENTARY AFFAIRS (SHRI B.K. HANDIQUE)

(a) to (e): As per para 7 of the Drugs (Prices Control) Order, 1995 (DPCO 95), in the case of a Scheduled imported formulation, the landed cost shall form the basis for fixing its price alongwith such margin to cover selling expenses and distribution expenses including interest and importer's profit which shall not exceed 50% of the landed cost. The "landed cost" means the cost of import of a formulation inclusive of the customs duty and clearing charges.

The office of DCG(I) has not issued any non-availability certificate to M/s. Novartis. However, the office of DCG(I) had clarified NPPA that the product Vitalux as "New Drug" has been permitted to M/s. Novartis to import and market in the country under Rule 122A of Drugs and Cosmetics Act on 12.4.2007 as M/s. Novartis was the only applicant with the said formulation.

The National Pharmaceutical Pricing Authority (NPPA) has allowed 35% Maximum Allowable Post Manufacturing Expenses (MAPE) while fixing the price of Vitalux on the basis of the application for price fixation for Vitalux plus tablets of M/s. Novartis wherein the company itself claimed 35% MAPE.